REMARKS

Applicants appreciate the Examiner's thorough examination of the subject application and request reconsideration of the subject application based on the foregoing amendments and the following remarks.

Claims 1-37, 44, 46-63 and 74-89 are pending in the subject application.

Claims 38-43, 45 and 64-73 were previously canceled. These claims were withdrawn from consideration as the result of an Examiner's earlier restriction requirement. In view of the Examiner's restriction requirement, Applicants reserve the right to present the above-identified withdrawn claims in a divisional application.

Claims 1, 37, 46-63 and 74-89 stand rejected under 35 U.S.C. §102 and/or 35 U.S.C. §103.

Claims 1, 52, 74 and 75 were amended to put the claims in better form and to more clearly claim the present invention.

Claims 3 and 6-7 were amended for clarity and/or so as to be consistent with the language of the amended base claim and/or any intervening claim.

Claims 18, 84 and 85 were amended to correct typos and/or grammar.

Claim 44 was amended so as to be in dependent form and so as to depend from claim 1.

The amendments to the claims are supported by the originally filed disclosure.

35 U.S.C. §102 REJECTIONS

The Examiner rejected claims 1-6, 9-11, 16-23, 25, 28, 30, 33-35, 37, 47-48, 52-55, 57-58, 61-62 and 75-76 under 35 U.S.C. §102(b) as being anticipated by 35 U.S.C. §102(b) as being anticipated by Chosack et al. [WO 99/38141; "Chosack"]. Applicants respectfully traverse.

It is generally accepted that a claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference. *Verdegal Bros. v. Union Oil Co. of California*, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987). Or stated another way, "The identical invention must be shown in as complete detail as is contained in the ... claims. *Richardson v Suziki Motor Co.*, 868 F.2d 1226, 9 USPQ 2d. 1913, 1920 (Fed. Cir. 1989). Although identify of terminology is not required, the elements must be arranged as required by the claim. *In re Bond*, 15 USPQ2d 1566 (Fed. Cir. 1990). As the CAFC also has provided, in deciding the issue of anticipation, the trier of fact must identify the elements of the claims, determine their meaning in light of the specification and prosecution history, and identify *corresponding elements* disclosed in the allegedly anticipating reference (emphasis added, citations in support omitted). *Lindemann Maschinenfabrik GMBM v. American Hoist and Derrick Company et al.*, 730 F. 2d 1452, 221 USPQ 481,485 (Fed. Cir. 1984).

As indicated herein, claims were amended in the instant amendment. Thus, the following discussion refers to the language of the amended claims; however, only those amended features specifically relied upon to distinguish the claimed invention from the cited prior art shall be considered as being made to overcome the cited reference.

As previously indicated by Applicants Chosack had been cited earlier during prosecution also in connection with a prior §102(b) rejection, which prior rejection was withdrawn. As the presently pending claims would appear to be narrower in scope than the earlier claims where the rejection had been withdrawn, Applicants would submit that the present claims remain distinguishable from Chosack. Notwithstanding the foregoing, Applicants offer the following additional observations as to the following groups of claims.

Claims 1-6, 9-11, 16-23, 25, 28, 30, 33-35, 37, & 47-48

In claim 1, Applicants claim a simulator system including a manikin and a medical device that simulates the use and movement of the medical device in a simulated body cavity or lumen of the manikin. The manikin includes the simulated body cavity or lumen and an interface

device. The medical device has a first end for manipulation by a first user and a portion having a second end that is insertable into the simulated body cavity or body lumen.

The *interface device* is configured to receive the medical device portion having the second end and to also interface with the simulated body cavity or lumen and **includes an active directional force feedback mechanism**. The *active directional force feedback mechanism* is configured so as to **exert a directional force directly on the medical device portion in response to a feedback signal received by the force feedback mechanism**.

Such a simulator system also includes a computational engine embodying physically based modeling using finite element methodology, the computational engine simulating interactions between the medical device and body cavity or lumen, the interactions relating to the manipulation of the medical device by the first user. Also, *the computational engine* **models interactions** between the medical device and the body cavity or lumen in three-dimensions, **computes forces that would arise from interactions** between the medical device and body cavity or lumen and **outputs feedback signals** corresponding to the computer forces **to the active directional force feedback mechanism**. In this way, the computed forces are feedback to the user so that they receive a force feedback corresponding to that which would arise from an interaction between the medical device and body cavity or lumen.

In the above-referenced Office Action it is asserted, *inter alia*, that Chosack describes that "the manikin includes an interface device configured to receive the medical device portion having a second end and to interface with the simulated body cavity or lumen (124)" it is also asserted that the interface device includes an active directional force feedback mechanism that exerts a directional force on the medical device in response to a feedback signal received by the force feedback mechanism" with reference to page 10, lines 4-13 of Chosack. Applicants respectfully disagree that Chosack describes the interface device as presently claimed pre- or post amendment.

It would appear from the foregoing excerpts from the above-referenced Office Action, that the feature allegedly corresponding to the interface device in Chosack is the element

identified by reference numeral 124. As can be seen from the following excerpt from Chosack (see pg. 21, l. 3-12), the element being identified by reference numeral 124 **is not a device** but **it is** rather merely **a hole** or opening in then manikin.

> Figures 5A and 5B illustrate the mechanical aspects of an exemplary simulated gastro- intestinal tract according to the present invention. A cut-away view of a mannequin 114 is shown in Figure 5A. Preferably, mannequin 114 is about one meter wide, which is within the dimensions of an actual human subject. A simulated gastro-intestinal tract 116 is shown within mannequin 114. For the purposes of clarity, simulated gastro- intestinal tract 116 includes only the colon, it being understood that this is not meant to be limiting in any way. Simulated gastro-intestinal tract 116 is connected to a transmitter 118 and a signal processing device 120, also placed within mannequin 114. As shown, a simulated endoscope 122 can be inserted into mannequin 114 through **an opening 124**. In this case, since the simulation is for endoscopy of the colon of the subject, **opening 124 simulates the rectum** of the subject. (bold type added for emphasis)

As also can be seen from the foregoing excerpt, the element in Chosack that one might consider as corresponding to the simulated body cavity or lumen in the manikin is the simulated gastro-intestinal tract 116 within the mannequin 114.

As set forth in claim 1, *the interface device* (i) is configured to receive the medical device portion having the second end and to also interface with the simulated body cavity or lumen and (ii) *includes an active directional force feedback mechanism*. It is further provided in claim 1 *that* the directional force feedback mechanism *is configured* so as **to exert a directional force on the medical device in response to a feedback signal received by the force feedback mechanism**. In the foregoing amendment, Applicants amended claim 1 for clarity to provide that the directional force is being exerted directly on the medical device portion in response to a feedback signal received by the force feedback mechanism.

As can be seen from the attached definitions of the word device, a device is a mechanism or piece of equipment that is designed to perform a particular task or function. At least as to claim 1, it is clear that *the interface device* thereof is supposed to be carry out the functions of (i)

receiving the medical device portion having the second end, (ii) *interfacing* with the simulated body cavity or lumen and (iii) **exerting a directional force on the medical device in response to a feedback signal received by the force feedback mechanism**. It is abundantly clear that the opening 124 in the manikin, while it can receive the medical device portion having the second end, does not in any other way correspond to the functions being carried out by the interface device of the claimed invention.

Also, and as previously indicated by Applicants, the discussion in Chosack (page 10, l. 4-22 thereof) provides that the simulated gastrointestinal tract includes a tactile feedback system that provides tactile feedback according to the movement of the simulated endoscope within the physically simulated organ. In Chosack, the simulated organ is a physical representation of the organ being simulated, not a virtual organ. As can be seen from the following excerpt from Chosack that the system described therein is made up of a physical model and a virtual model; not only a virtual model.

> The system of the present invention features both a physical model and a virtual model for the simulation of the medical procedure of endoscopy. The physical model includes a mannequin into which the simulated endoscope is inserted. A simulated organ is located within the mannequin. For example, if the simulated organ is the gastro- intestinal tract, the organ may optionally include a simulated rectum and a simulated colon for simulating the procedure of flexible gastro-endoscopy. Optionally and preferably, the simulated organ may optionally include a simulated mouth and upper gastro-intestinal tract. The simulated endoscope is inserted into the simulated gastro-intestinal tract. The simulated gastro-intestinal tract includes a tactile feedback system for providing realistic tactile feedback according to the movement of the simulated endoscope within the simulated organ.
>
> The virtual model provides a "virtual reality" for the simulation of images from the endoscope. In an actual endoscopic medical procedure, a camera at the tip of the actual endoscope returns images from the gastro-intestinal tract of the human patient. These images are then viewed by the physician performing the endoscopic procedure, thereby providing visual feedback to the physician. The system of the present invention provides a "virtual reality" for the realistic simulation of this visual feedback. This virtual reality enables the real-time display of realistic images of the gastro-intestinal tract on a video monitor

> according to the manipulations of the simulated endoscope, preferably in such a manner that the tactile and visual feedback are linked as they would be in a human patient.

It also is clear from the following excerpt from Chosack (page 25, l 3-12) that the simulation system described therein utilizes the structure of the physical model for causing the tactile feedbacks to the user for interactions between the medical device and the body cavity or lumen.

> Figure 7C shows simulated endoscope 146 after insertion within the second embodiment of a simulated gastro-intestinal tract 160. Simulated gastro-intestinal tract 160 is preferably constructed from a rigid material. In addition, simulated gastro-intestinal tract 160 preferably has the general anatomical shape and features of an actual gastro-intestinal tract for two reasons. First, the general anatomical shape can be more easily contained within the mannequin because of its bends and turns. Second, the general anatomical shape can provide gross tactile feedback. For example, as any endoscope is inserted more deeply into the colon, the shape of the colon causes the tactile sensations to be altered as the endoscope moves around a bend in the colon. Thus, the general anatomical shape is more useful for an effective simulation.

Thus, as the simulated medical device in Chosack moves through the physical model of the colon or simulated gastro-intestinal tract, the endoscope can contact different portions of the colon/gastro-intestinal tract (see page 19, lines 8-10 thereof).

Chosack also describes (see pages 22-23 and Fig. 6A) providing a plurality of motion boxes 134 that are dispose at intervals along the *outer* surface of the gastro-intestinal tract. Each of these motion boxes has at least one, and preferably a plurality of, servo motors 80. Each such servo-motor 80 is connected to a piston 136 which is at least in mechanical contact with the external surface of the gastro-intestinal tract. Preferably the piston 136 is mechanically coupled or attached to a portion of the external surface for easier manipulation.

It is further described in Chosack that each piston contacts the external surface of the gastro-intestinal tract in order to manipulate the material of the gastro-intestinal tract so that this material comes into contact with the simulated endoscope and so as a force is thereby exerted

against the endoscope to provide the so-called tactile sensations. It is asserted therein that these movements alter the position of the material of the gastro-intestinal tract causing forces to be exerted against the simulated endoscope.

In sum, the opening 124 in the manikin of Chosack is not an interface device as that term is used in the claims or in customary language. Also, the functionality in Chosack that causes forces to be exerted on the endoscope during a simulated position is the plurality of movement boxes 134 that act on the external surface of the simulated physical model of the gastro-intestinal tract so this material contacts the simulated endoscope. These also do not correspond to an interface device that interfaces the simulated body cavity or lumen in the manikin.

Applicants also respectfully disagree with the assertion that the position based discussion corresponds in any way to the computational engine as set forth in the claims. In the simulated system of the present invention, the direction and motion of the medical (*e.g.*, catheter) is not influenced by distal end contact with a physical model as is described in Chosack, but is determined by a finite element computational model based on assumptions of the vascular anatomy characteristics and physical characteristics of the medical device/catheter contacting a physical anatomical model. In other words, the computational model of the present invention is used to predict the directionality and forward motion of the distal end of the medical device/catheter within the simulated model. As also described in the subject application, in the simulated system of the present invention, resistance to forward motion of the medical device/catheter is largely due to the friction exerted along the surface if the medical device as is passes through the interface device. In contrast to the present invention and as described for the Chosack model, the distal end of the simulated endoscope interacts with the physical model of the gastro-intestinal tract/colon and is influenced by forces exerted by piston like devices located on the external surface of the physical model of the gastro-intestinal tract/colon.

Thus, Chosack describes and teaches a system, that has to embody a physical and virtual model of the gastro-intestinal tract and which also simulates movement of the endoscope within

the gastro-intestinal tract. While the functions being performed might appear to be similar, the structure of the system of the present invention is different from that described in Chosack. Therefore, Chosack does not anywhere describe or disclose a simulator system as is set forth in claim 1.

In the foregoing amendment claim 1 was amended so as to put the claim in better form. Specifically, the language of the pending claim was re-organized for clarity. Also, claim 1 was amended in the interests of advancing prosecution so as to provide that the directional force being exerted by the directional force feedback mechanism is being exerted directly on the medical device. From the foregoing remarks and excerpts from Chosack it is clear that the pistons 136 do not act directly on the endoscope.

As to claims 2-6, 9-11, 16-23, 25, 28, 30, 33-35, 37, and 47-48, each of these claims depends (directly or ultimately) from claim 1, which claim is considered to be in allowable form. Thus, each of claims 2-6, 9-11, 16-23, 25, 28, 30, 33-35, 37, and 47-48 is considered to be allowable at least because of the dependency from an allowable base claim. This shall not be considered to be an admission that claims 2-6, 9-11, 16-23, 25, 28, 30, 33-35, 37, and 47-48 would not be separately patentable from Chosack.

For example, claim 3 includes the further limitations that the active directional force feedback mechanism includes a rolling element that is coupled to the medical device portion having the second end, that an internal surface of the simulated cavity or lumen in the manikin includes an oblique slot and that the directional force feedback mechanism is arranged so that the rolling element is receivable in the oblique slot. As can be seen from the foregoing discussion regarding the motion boxes 134 of Chosack, the pistons 136 contact the exterior surface and do not project through the physical model of the gastro-intestinal tract 116.

It is respectfully submitted that claims 1-6, 9-11, 16-23, 25, 28, 30, 33-35, 37, and 47-48 are patentable over the cited reference for the foregoing reasons.

Claims 52-55, 57-58 & 61-62

Applicants respectfully submit that the foregoing remarks distinguishing claim 1 from Chosack also at least apply to distinguish the method for simulating the use and movement of a medical device as set forth in claim 52 from Chosack.

As to claims 53-55, 57-58 and 61-62, each of these claims depends (directly or ultimately) from claim 52, which claim is considered to be in allowable form. Thus, each of claims 53-55, 57-58 and 61-62 is considered to be allowable at least because of the dependency from an allowable base claim. This shall not be considered to be an admission that claims 53-55, 57-58 and 61-62 would not be separately patentable from Chosack.

It is respectfully submitted that claims 52-55, 57-58 and 61-62 are patentable over the cited reference for the foregoing reasons.

Claims 75-76

Applicants respectfully submit that the foregoing remarks distinguishing claim 1 from Chosack also at least apply to distinguish the simulator system as set forth in claim 75 from Chosack.

As to claim 76, this claim depends from claim 75, which claim is considered to be in allowable form. Thus, claim 76 is considered to be allowable at least because of the dependency from an allowable base claim. This shall not be considered to be an admission that claim 76 would not be separately patentable from Chosack.

It is respectfully submitted that claims 75 and 76 are patentable over the cited reference for the foregoing reasons.

It is respectfully submitted that for the foregoing reasons, claims 1-6, 9-11, 16-23, 25, 28, 30, 33-35, 37, 47-48, 52-55, 57-58, 61-62 and 75-76 are patentable over the cited reference and

thus, satisfy the requirements of 35 U.S.C. 102(b). As such, these claims, including the claims dependent therefrom are allowable.

35 U.S.C. §103 REJECTIONS

Claims 49 and 77-87 stand rejected under 35 U.S.C. §103 as being unpatentable over Chosack et al. [WO 99/38141; "Chosack"] in view of Cai et al., Parametric Modeling Based on Multi-Layered Approach for Design and Validation of Catheterization Devices [citations omitted; "Cai"]; claims 7, 8, 63, 74, 88 and 89 stand rejected as being unpatentable over Chosack in view of Rosenberg et al. [U.S. Patent 5,959,613; "Rosenberg"]; claims 12-15 stand rejected as being unpatentable over Chosack in view of Belson, et al. [U.S. Patent 6,610,007; "Belson"]; claims 24 and 32 stand rejected as being unpatentable over Chosack in view of Simon et al. [U.S. Patent 6,470,207; "Simon"] and Saunders [U.S. Patent 6,572,376]; claims 26, 27, 29 and 56 stand rejected as being unpatentable over Chosack in view of Pollak, et al. [U.S. Patent 66,106,297; "Pollak"] and Issenberg, et al. Simulation Technology for Health Care Professional Skills Training and Assessment [citations omitted; "Issenberg"]; claim 36 stands rejected as being unpatentable over Chosack in view of Pollak, et al. [U.S. Patent 6,106,297; "Pollak"] and Issenberg, et al. Simulation Technology for Health Care Professional Skills Training and Assessment [citations omitted; "Issenberg"] and further in view of Hon [U.S. Patent 6,074,213]; and claims 44, 46, 50, 51, 60 and 59 stand rejected as being unpatentable over Chosack in view of Merrill [U.S. Patent 6,106,301] for the reasons provided on pages 8-18 of the above-referenced Office Action.

It is respectfully submitted that each of the foregoing claims is considered to be patentable over the identified combination of references as the primary reference (*i.e.*, Chosack) does not disclose the claimed invention and the secondary, tertiary, etc. references do not make up for the deficiencies in the primary reference identified in the discussion above concerning the §102(b) rejection.

As such, at least for this reason each of claims 7, 8, 12-15, 24, 26, 27, 29, 32, 36, 44, 46, 49-51, 56, 59, 60 63, 74, and 77-89 claims is considered to be patentable over the identified combination of references. These brief remarks, however, shall not be construed as an admission that these claims are not otherwise patentable over the cited art.

As provided in MPEP 2143.01, obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. *In re Fine*, 837 F. 2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988); *In re Jones*, 958 F. 2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). As provided above, the references cited, alone or in combination, include no such teaching, suggestion or motivation.

Furthermore, and as provided in MPEP 2143.02, a prior art reference can be combined or modified to reject claims as obvious as long as there is a reasonable expectation of success. *In re Merck & Co., Inc.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 19866). Additionally, it also has been held that if the proposed modification or combination would change the principle of operation of the prior art invention being modified, then the teachings of the references are not sufficient to render the claims *prima facie* obvious. Further, and as provided in MPEP-2143, the teaching or suggestion to make the claimed combination and the reasonable suggestion of success must both be found in the prior art, not in applicant's disclosure. *In re Vaeck*, 947 F.2d 488, 20 USPQ2d 1438 (Fed. Cir. 1991). As can be seen from the forgoing discussion regarding the disclosures of the cited references, there is no reasonable expectation of success provided in the reference(s). Also, it is clear from the foregoing discussion that the modification suggested by the Examiner would change the principle of operation of the device disclosed in the principal reference.

Although a prior art device "may be capable of being modified to run the way the apparatus is claimed, there must be a suggestion or motivation in the reference to do so." *In re Mills* , 916 F. 2d, 680, 682; 16 USPQ 2d 1430, 1432 (Fed. Cir. 1990). As the Federal circuit also

has stated, "[t]he mere fact that the prior art may be modified in the manner suggested by the Examiner does not make the modification obvious unless the prior art suggested the desirability of the modification." *In re Fritch*, 972 F.2d 1260,1266, 23 USPQ2d 1780, 1783-84 (Fed. Cir. 1992).

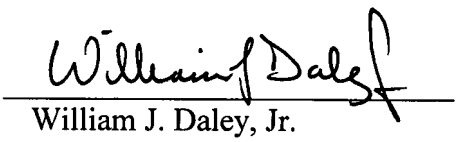
It is respectfully submitted that for the foregoing reasons, claims 7, 8, 12-15, 24, 26, 27, 29, 32, 36, 44, 46, 49-51, 56, 59, 60 63, 74, and 77-89 are patentable over the cited reference(s) and thus, satisfy the requirements of 35 U.S.C. §103. As such, these claims are allowable.

It is respectfully submitted that the subject application is in a condition for allowance. Early and favorable action is requested.

Applicants believe that additional fees are not required for consideration of the within Response. However, if for any reason a fee is required, a fee paid is inadequate or credit is owed for any excess fee paid, the Commissioner is hereby authorized and requested to charge Deposit Account No. **04-1105**.

Respectfully submitted,
Edwards & Angell, LLP

Date: August 16, 2007

By: 

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Dictionary

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Dictionary Thesaurus Translations

A B C D E F G H I J K L M N O P Q R S T U V W X Y Z

- développé
- deverbative
- Devi
- deviance
- deviant
- deviate
- deviation
- deviationism
- **device**
- devil
- devil-may-care
- devil's advocate
- devil's club
- devil's coach-horse
- devil's darning needle
- devil's food cake
- Devil's Island

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See pronunciation key

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device

device

de·vice [di v□ss] (*plural* de·vices)

noun

Definition:

1. tool or machine: a tool or machine designed to perform a particular task or function

2. ploy: a way of achieving something, especially a clever or dishonest way

3. explosive object: a bomb or something that causes an explosion or fire

4. literary or dramatic tool: something designed to create a particular effect in a literary or dramatic work, or to evoke a particular response from a reader, listener, or viewer
- *a familiar cinematic device*

5. emblem or motto: an emblem or motto, or a combination of the two, especially when used in heraldry
- *a heraldic device*

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6. ornamental design: an ornamental pattern or design, e.g. in embroidery

[13th century. < Old French *devis* "division, contrivance," *devise* "plan" < Latin *dividere* (see divide)]

leave somebody to his *or* her own devices to let somebody do as he or she wishes, instead of giving the person direction or assistance

device

5 entries found for **device**.
To select an entry, click on it.

device
charge-coupled device
intrauterine device
point-device
ventricular assist device
Go

Main Entry: **de·vice**
Pronunciation: di-'vIs
Function: *noun*
Etymology: Middle English *devis, devise,* from Anglo-French, division, plan, from *deviser* to divide, regulate, tell -- more at DEVISE

1 : something **devised** or contrived: as **a** (1) **:** PLAN, PROCEDURE, TECHNIQUE (2) **:** a scheme to deceive **:** STRATAGEM, TRICK **b :** something fanciful, elaborate, or intricate in design **c :** something (as a figure of speech) in a literary work designed to achieve a particular artistic effect **d** *archaic* **:** MASQUE, SPECTACLE **e :** a conventional stage practice or means (as a stage whisper) used to achieve a particular dramatic effect **f :** a piece of equipment or a mechanism designed to serve a special purpose or perform a special function <an electronic *device*>

2 : DESIRE, INCLINATION <left to my own *devices*>

3 : an emblematic design used especially as a heraldic bearing

Pronunciation Symbols